RECORD AND BRIEFS

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In The

Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,

Petitioner,

v.

LEXMARK INTERNATIONAL, INC.,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICUS CURIAE* PROFESSOR FREDERICK M. ABBOTT IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae is Frederick M. Abbott, Edward Ball Eminent Scholar Professor of International Law at Florida State University College of Law. Professor Abbott has researched and written extensively in the fields of international intellectual property, international trade and public health law. For more than twenty years (1993-2014) he served as Rapporteur for the Committee on International Trade Law of the International Law Association, during which tenure he organized meetings of experts and prepared two detailed reports on the subject of parallel importation. He served as advisor to the government of South Africa on trade and intellectual property issues in 2000-01 as that government successfully defended a complaint initiated by originator pharmaceutical industry enterprises challenging South Africa's adoption of international exhaustion of patents. He has served as consultant to the World Health Organization on matters relating to intellectual property, trade and public health for many years. He recently served as a member of the Expert Advisory Group to the United Nations Secretary General's High Level Panel on Access to

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[1] Pursuant to Sup. Ct. R. 37.3(a), *Amici* certify that Respondent has given blanket consent to the filing of *Amicus* briefs in support of either party, and Petitioner has consented to the filing of this brief in correspondence on file with the Clerk. Pursuant to Sup. Ct. R. 37.6, *Amicus* certifies that no counsel for any party authored this brief in whole or in part, no party or party's counsel made a monetary contribution to fund its preparation or submission, and no person other than *Amicus* made such a monetary contribution.

Medicines. He is Co-Chair of the Global Health Law Committee of the International Law Association. Professor Abbott is co-author of a widely-used course book on international intellectual property law, as well as co-author of a book on global pharmaceutical policy.

This *Amicus* favors international exhaustion of patent rights under the U.S. Patent Act. Professor Abbott is particularly interested in measures that may help to ameliorate the burdens imposed on the American public by high pharmaceutical prices. Professor Abbott argues that parallel importation of patented pharmaceutical products may aid in achieving that objective.

SUMMARY OF ARGUMENT

Up until the decision of the Federal Circuit in *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), the preponderant weight of judicial authority in the United States, including of this Court, was in favor of international exhaustion of patent rights. The decision of the Federal Circuit for which certiorari has been granted, *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d 721 (Fed. Cir. 2016), affirms its *Jazz Photo* decision, and it would continue enabling post-sale restrictions based on patents. This *Amicus* urges the Court to overrule the Federal Circuit on both aspects of that decision. This means adopting a rule of international exhaustion of patent rights for the United States consistent

with pre-*Jazz Photo* jurisprudence, and prohibiting post-sale restrictions based on patent.

A fundamental flaw in the approach of the Federal Circuit involves its reasoning that a rule of territoriality of patent rights precludes U.S. courts from taking into account activities of U.S. patent owners outside the United States. The international agreements governing the international patent system do not prescribe such a rule of territoriality. By recognizing that first sales under the authority of U.S. patent owners outside the United States exhaust U.S. patent rights, this Court would not in any sense be subjecting U.S. patent owners to application of foreign law, and would not be impinging on the authority of foreign sovereigns. The rule of independence of patents prescribed by the Paris Convention on the Protection of Industrial Property provides that acts taken by patent authorities in one country do not affect patent rights in other Paris countries. Recognition by this Supreme Court that first sales in foreign countries exhaust U.S. patent rights would not affect patents granted outside the United States. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights permits the United States to adopt international exhaustion of patents. Contrary to the view of the Federal Circuit, three trade agreements entered into by the United States that address first sales outside the United States at most require this country to provide the means to enforce contracts limiting imports. Adoption by this Court of a rule of international patent exhaustion would not contravene any such agreement.

This *Amicus* supports the general case for international exhaustion of patent rights and elimination of patent-based post-sale restrictions. This *Amicus* has expertise in the global regulation of pharmaceutical products, including with respect to patents and other forms of intellectual property, and much of this brief addresses the exhaustion issue with respect to patented pharmaceuticals.

By allowing parallel importation of U.S.-patented pharmaceutical products, this Court would enable price competition from imported FDA-approved products manufactured outside the United States with the consent of their U.S. patent owners. The introduction of parallel import products is likely to have a modest downward pricing effect. The United States is a large pharmaceutical market, and the supply of U.S. patented pharmaceuticals from abroad is, and will remain, limited. The fact that parallel imported pharmaceutical products are likely to have a modest effect on U.S. prices is not reason to preclude them. Parallel imports may be one useful and important step toward moderating patented pharmaceutical prices in the United States.

The United States should continue to encourage low-priced supply of U.S.-patented pharmaceutical products to low income countries. Suppliers of such products may restrict exports from low income countries by contract, and such contractual provisions should be enforceable, including in the United States. Governments in low income countries may adopt legislation to limit exports of products supplied under discounted pricing programs consistently with WTO

rules. If necessary, the United States could also limit imports from designated low income countries, or imports previously supplied under designated programs, under WTO rules. The United States should not forgo the benefits of a rule of international exhaustion of patent rights for the limited purpose of enabling price discrimination with respect to one specific category of products.

ARGUMENT

The Petition for Certiorari by Impression Products and the brief of the Department of Justice filed in support of the petition amply demonstrate that the Federal Circuit decision below misconstrued Supreme Court jurisprudence regarding post-sale restrictions based on patents, and should be overturned. This *Amicus* brief focuses on that part of the Federal Circuit decision addressing whether *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. ___, 133 S.Ct. 1351 (2012), effectively overruled its decision in *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001). In *Jazz Photo*, the Federal Circuit announced a new rule of "national exhaustion" of patent rights[2] for

[2] In customary usage, "national exhaustion" of intellectual property rights (IPRs), including patents, is used to refer to a first sale doctrine in which only first sales occurring within the national territory of the country where the doctrine operates exhaust the rights of the IPR owner. "International exhaustion" is used to refer to a first sale doctrine in which a first sale anywhere in the world exhausts the rights of the IPR owner. "Regional exhaustion," which is not otherwise discussed in this *Amicus* Brief

the United States without a hint of acknowledgment that in doing so it rejected contrary precedent of this Court and several Circuits. In its decision below, *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d 721 (Fed. Cir. 2016), the Federal Circuit affirmed its *Jazz Photo* decision, repeating its initial error. This Court should correct that mistake.

This *Amicus* is particularly concerned with addressing arguments that have been presented by patent-owning pharmaceutical industry groups in opposition to a rule of international patent exhaustion as such arguments are unpersuasive. A rule of international patent exhaustion should have the beneficial effect of placing downward pressure on pharmaceutical prices in the United States. Such downward pressure would have a beneficial impact on public health budgets as well as on individual patients/consumers. There is no reason to protect pharmaceutical industry patent owners from competition with their own products. The interests of low income countries in securing specially priced products can be protected through contract and, where necessary, government regulation. Such interest does not suggest or mandate recognition of post-sale restrictions based on patents.

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refers to a first sale doctrine in which a first sale anywhere within a regional arrangement exhausts the rights of the IPR owner within the territory of that arrangement. *See* FREDERICK M. ABBOTT, THOMAS COTTIER AND FRANCIS GURRY, INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY, Aspen Publishers, 3d ed., 2015, at pgs. 98-99 (hereinafter "Abbott, Cottier & Gurry").

I. U.S. and International Law Support International Exhaustion

A. References to Territoriality of Patent Law Require Clarification

In its decision below, 816 F.3d at 764-65, the Federal Circuit emphasized that patent law is territorial, referring to precedent of this Supreme Court, *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 127 S.Ct. 1746, 167 L.Ed.2d 737 (2007). However, the Federal Circuit's unqualified reference does not accurately reflect the way in which the international patent system is governed, or the context in which *Microsoft v. AT & T* was decided.

Neither this Court nor the Federal Circuit have held that activities of U.S. patent owners outside the United States may not affect the application of U.S. patent law within the United States. Neither the Paris Convention on the Protection of Industrial Property (hereinafter "Paris Convention"),[3] the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "WTO TRIPS Agreement"),[4] nor

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[3] Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979). Source: www.wipo.int, including ratifications by United States through the Stockholm Act (1967), accessed January 12, 2017 (hereinafter "Paris Convention").

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Apr. 15, 1994, in WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999) [hereinafter "WTO TRIPS Agreement"].

other international agreements to which the United States is party preclude the consideration of foreign activities in the application of U.S. domestic patent law. Without doubt these international agreements allow adoption of a rule of international exhaustion with respect to patents.

B. Independence of Patents

The Paris Convention prescribes a rule of independence of patents (*see* FREDERICK M. ABBOTT, THOMAS COTTIER AND FRANCIS GURRY, INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY, Aspen Publishers, 3d ed., 2015, at pgs. 92-97).[5] This rule provides that the patent law and administrative decisions of each Paris Convention member state are independent of those of other states, and that the decisions of the authorities in one state will not determine the effect of patents in another state. *See,*

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[5] The text of the Paris Convention provides:

Article 4bis

Patents: Independence of Patents Obtained for the Same Invention in Different Countries

(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.

(2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.

e.g., *Cuno, Inc. v. Pall Corporation*, 729 F. Supp. 234, 239 (E.D.N.Y. 1989). Patents are independent of each other principally so as to prevent abuse by courts or administrative authorities in one country of patents and patentees in another country.

C. Territoriality and Comity

The Paris Convention does not prescribe a rule of territoriality of patents. Abbott, Cottier & Gurry, at 81. To the extent that courts in one Paris country refuse to extend rights of patentees to activities in other Paris countries, this is a matter of judicial accommodation similar to the accommodation represented by act of state doctrine.[6] It is a matter of comity. Nothing in the Paris Convention directs that the United States must refuse to allow its patentees to sue each other for infringement based on activities taking place in foreign countries. The Federal Circuit itself has acknowledged that activities taking place outside the United States can form part of an infringement within the United States in *NTP, Inc. v. Research in Motion, Inc.*, 418 F.3d 1282 (Fed. Cir. 2005) (addressing conduct outside the

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[6] As explained by this Court in *Banco Nacional de Cuba v. Sabbatino*, 84 S.Ct. 923, 934 (1964), quoting from *Underhill v. Hernandez*, 168 U.S. 250, 252, 18 S.Ct. 83, 84, 42 L.Ed. 45 (1897):

> "'Every sovereign state is bound to respect the independence of every other sovereign state, and the courts of one country will not sit in judgment on the acts of the government of another, done within its own territory.'"

United States in affirming a finding of patent infringement).[7]

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[7] The Federal Circuit said:

"The question before us is whether the using, offering to sell, or selling of a patented invention is an infringement under section 271(a) if a component or step of the patented invention is located or performed abroad. . . ."

" . . . it is unclear from the statutory language how the territoriality requirement limits direct infringement where the location of at least a part of the 'patented invention' is not the same as the location of the infringing act."

* * *

"this case involves a system that is partly within and partly outside the United States and relates to acts that may be occurring within or outside the United States"

* * *

"Decca [*Decca Ltd. v. United States*, 210 Ct.Cl. 546, 544 F.2d 1070 (Fed. Cl. 1976)] provides a legal framework for analyzing this case. As our predecessor court concluded, infringement under section 271(a) is not necessarily precluded even though a component of a patented system is located outside the United States."

* * *

"The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, i.e., the place where control of the system is exercised and beneficial use of the system obtained. *See Decca*, 544 F.2d at 1083. Based on this interpretation of section 271(a), it was proper for the jury to have found that use of NTP's asserted system claims occurred within the United States. RIM's customers located within the United States controlled the transmission of the originated information and also benefited from such an exchange of information. Thus, the location of

D. Due Regard for Sovereign Prerogative

This Supreme Court has held, and emphasized as recently as *Microsoft v. AT & T*, that the U.S. Patent Act governs activities that take place within the territory of the United States insofar as the enforcement of rights of U.S. patent owners (i.e. to preclude third parties from infringing their U.S. patent rights).

> "It is the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country." *Microsoft v. AT & T*, 550 U.S. at 441.

Third parties are prevented from making, using or selling within, or importing into, the territory of the United States without authority.[8] There is a presumption that U.S. patent owners may not preclude third parties from undertaking acts outside the territory of the United States based on their U.S. patents, although Congress may well legislate contrary to that presumption. This Supreme Court has said that an effort by the United States or its courts to enforce U.S. patent rights abroad would impinge on the sovereign authority of

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the Relay in Canada did not, as a matter of law, preclude infringement of the asserted system claims in this case." 418 F.3d at 1315-17.

[8] Section 271(a) of the Patent Act provides: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. §271 – Infringement of patent.

Paris Convention, *supra* note 3.

other governments to control activities taking place within their own territory. 550 U.S. at 455.

This limitation on the enforcement of patent rights should not be conflated with the authority of U.S. courts to take into consideration acts taking place outside the United States in terms of enforcement of patents within the territory of the United States. Congress, has in fact, expressly recognized this scope of authority in adopting 35 U.S.C. §271(f) which this Supreme Court interpreted in *Microsoft v. AT & T*. Congress determined that it possessed such authority when it adopted the provision making it an act of infringement, *inter alia*, to export components with the knowledge that they would be combined outside the United States in a way that would infringe a U.S. patent if the combination was performed within the United States.

There is nothing about the international exhaustion of patent rights that impinges upon decisions of foreign sovereigns, or that is dependent on decisions made by foreign sovereigns (including their regulatory authorities). It is wholly a question of U.S. law.[9] The

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[9] The Supreme Court might wish to look at the decision by the Supreme Court of Japan in the *BBS Wheels* case in the context of this case. *BBS Kraftfahrzeugtechnik AG and BBS Japan, Inc. v. Rasimex Japan, Inc.*, Supreme Court Heisei 7(o) No. 1988 (July 1, 1997), J. of S.Ct., No. 1198, translated excerpt reprinted in Abbott, Cottier & Gurry, at 240-42 (July 15, 1997), pgs. 8-10. In *BBS Wheels*, the holder of a patent in Japan, with a parallel patent in Germany, sought to prevent the importation of aluminum alloy wheels into Japan, notwithstanding a first sale of those wheels in Germany. The Japanese Supreme Court observed that this was not a matter of determining German law or its consequences, but

United States will be deciding which products may be imported into the United States without suffering claims of patent infringement.[10]

E. Territoriality and Independence as Distinct Concepts

The idea that the United States should not allow its patents to be controlled or governed by foreign patent law, on one side, and the idea that the United States should not allow its patents to be affected by activities occurring abroad, on the other, involve distinct concepts. Indeed, in *Boesch v. Graff*, 133 U.S. 697, 10 S.Ct. 378 (1890), this Court applied the former principle in refusing to recognize exhaustion of the United States patent based on application of German law (i.e., the prior user right). But, that case did not involve an

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rather a matter of Japanese law. Namely, did the Japanese Patent Act recognize that the rights of a Japanese patent owner with respect to a product first placed on the market outside of Japan were exhausted by the first sale? The Japanese Supreme Court responded in the affirmative, that Japanese patent rights are exhausted by a first sale outside Japan, although the Japanese patent owner may through contract and notice restrict subsequent importation into Japan.

[10] Many acts taking place outside the United States are the subject of federal law, actionable within the United States. *See, e.g., W.S. Kirkpatrick & Co. v. Environmental Tectonics Corp., Int'l*, 493 U.S. 400, 110 S.Ct. 701, 704, 107 L.Ed.2d 816 (1990), in reference to the Foreign Corrupt Practices Act of 1977 (FCPA), 15 U.S.C. §§78dd-1, 78dd-2. When this Court enforces a criminal penalty against a U.S. person that bribes a foreign government official, the act that is the subject of the penalty took place outside the United States, and is not dependent on whether the foreign country penalizes the local conduct.

action undertaken by or with the consent of the U.S. patentee in Germany. The Supreme Court was not addressing the exercise of rights by a U.S. patent owner abroad and the effect that might have on its U.S. patent rights.

F. Congress

The parties in this case agree that the U.S. Congress has not expressly spoken on the question whether the decision by a U.S. patent owner to place its invention on the market in a foreign country exhausts its patent rights within the United States. The Patent Act does not expressly address whether a decision by a U.S. patent owner to first sell its invention abroad exhausts its patent rights in the United States. There was long-standing judicial recognition – prior to *Jazz Photo* – that a first sale abroad exhausts patent rights. As noted *infra*, Congress adopted legislation post-*Jazz Photo* precluding USTR from including provisions addressing the international exhaustion question in trade agreements. Congress has authorized certain importation of prescription medicines from abroad subject to regulatory approval from HHS.[11] In doing so it

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[11] Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 – Dec. 8, 2003, 117 Stat. 2066, et seq. *See* U.S. Department of Health and Human Services, HHS Taskforce on Drug Importation, *Report on Prescription Drug Importation*, December 2004 [hereinafter "HHS Taskforce Report"].

did not expressly address the issue of patents. Congress has not suggested a presumption against international exhaustion of patents.

G. Trade Agreements and Their Effect

The multilateral agreements regulating patents to which the United States is a party allow adoption of a rule of international exhaustion. Although participants in the Uruguay Round negotiations agreed that the WTO TRIPS Agreement did not establish any mandatory rule of exhaustion,[12] this determination was brought into question in the late 1990s by a number of originator pharmaceutical companies and certain supporting governments in the context of challenges to the South African Medicines and Related Substances Control Amendment Act of 1997.[13] After the originator industry companies had formally withdrawn their challenge, the Members of the World Trade Organization made clear in the 2001 Doha Declaration on the TRIPS Agreement and Public Health, at paragraph 5(d):

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[12] *See* Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 JOURNAL OF INTERNATIONAL ECONOMIC LAW 607, 609 (1998).

[13] South Africa, Act. No. 90 of 1997: Medicines and Related Substances Control Amendment Act, 1997, Government Gazette, December 12, 1997, No. 18505. *See* Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 JOURNAL OF INTERNATIONAL ECONOMIC LAW 469, 471 (2002) [hereinafter "Abbott-Doha"].

> The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.[14]

The Doha Declaration represents an agreement among the parties to the WTO Agreements on interpretation of the WTO TRIPS Agreement.[15] Today, the proposition that each Member of the WTO is free to adopt its own rule of exhaustion is widely accepted, including by this Court.[16]

As observed by the Federal Circuit in its decision below, when the U.S. Congress approved the results of the Uruguay Round in the Uruguay Round Agreements Act,[17] it did so with assurance in the Executive Branch Statement of Administrative Action that the WTO TRIPS Agreement was not intended to modify U.S. law on the subject of parallel importation.[18]

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[14] WTO, Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/MIN(01)/DEC/2 (20 November 2001).

[15] Abbott-Doha, at 494-97.

[16] *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. ___, 133 S.Ct. 1351 (2013), Justice Ginsburg dissenting, at 1383-84.

[17] Uruguay Round Agreements Act, Pub. L. No. 103-465, §§532, 533, 108 Stat. 4809, 4983-90 (1994).

[18] *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d 721, 765 (Fed. Cir. 2016). Message from the President of the United States Transmitting the Uruguay Round Trade Agreements, Texts of Agreements Implementing Bill, Statement

Subsequent to U.S. adoption of the WTO TRIPS Agreement, USTR negotiated a few bilateral free trade agreements in which were incorporated provisions that obligated the parties to make provision against unauthorized importation of patented goods first placed on the market outside the country party, at least by providing for the enforcement of contractual restrictions.[19] The fact that these agreements included the option to recognize contractual restrictions, as opposed to enforcement based on patent rights, must have taken into account uncertainty within USTR and the federal government as to whether this Supreme Court would uphold the Federal Circuit's decision in *Jazz Photo*. As the Department of Justice has noted in its *Amicus* brief supporting the grant of certiorari in this case, subsequent to negotiation of these three trade agreements, Congress in its appropriations legislation precluded the incorporation by the Executive of equivalent provisions in subsequent trade agreements.[20]

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of Administrative Action and Required Supporting Statements, H.R. Doc. No. 316, 103d Cong., 2d Sess. (1994), reprinted in 1994 U.S.C.C.A.N. 4040, 4280.

[19] *Id.*, 816 F.3d at 765-66.

[20] Brief for the United States as *Amicus Curiae*, at 19, *citing, e.g.*, Science, State, Justice, Commerce, and Related Agencies Appropriation Act, 2006, Act of Nov. 22, 2005, Pub. L. No. 109-108, §631, 119 Stat. 2344, which provides:

> "Sec. 631. None of the funds made available in this Act may be used to include in any new bilateral or multilateral trade agreement the text of –
>
> (1) paragraph 2 of article 16.7 of the United States-Singapore Free Trade Agreement;

The Federal Circuit decision below is disingenuous in suggesting that adoption by the Supreme Court of a rule of international exhaustion would negate U.S. obligations in the three referenced free trade agreements. As the dissent in the case below observed, it is evident that recognizing the right of patent owners to enforce contracts would be adequate to satisfy U.S. obligations under these agreements because the agreements expressly provide that option.[21] The agreements do not entail an obligation to permit patent owners to bring infringement actions based on parallel imports.

Pursuant to the implementing acts for each of the three free trade agreements, there was no intention to change existing federal law except as otherwise expressly provided, and none of the implementing acts purported to modify the Patent Act regarding exhaustion. Pursuant to federal statute, the three free trade agreements are not self-executing or directly effective in the law of the United States.[22] The fact that the Congress has expressed a view that the provisions in the three agreements should not be incorporated in future U.S. trade agreements suggests that this Court would be acting most consistently with the will of Congress in refusing to create a rule of federal patent law based

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(2) paragraph 4 of article 17.9 of the United States-Australia Free Trade Agreement; or

(3) paragraph 4 of article 15.9 of the United States-Morocco Free Trade Agreement."

[21] *Id.*, Dyk dissenting, 816 F.3d at 785-86.

[22] *Id.*, Dyk dissenting, 816 F.3d at 785-86, at n. 14.

on these three free trade agreements. But, to be clear, there would be no inconsistency between a decision of this Court recognizing that contractual restrictions may limit imports to the United States and the provisions of the three trade agreements, which would not entail any change in federal law.

II. Policy Grounds Favoring International Exhaustion

There are several reasons why international exhaustion of patent rights is preferable to national exhaustion from the standpoint of the United States.

A. Price discrimination injures the American consumer

Allowing patent owners to block parallel imports is in effect a mechanism for enabling price discrimination among markets. If the holder of a patent in the United States can block the importation of products that it has first sold abroad, that patent holder may charge a higher price in the U.S. market for those products than it charges abroad.

The Federal Circuit considers that granting this authority to patent owners allows them to secure a level of patent reward or compensation commensurate with the income level and other market factors within the United States.[23] The Federal Circuit simply ignores

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[23] *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d at 760-62.

the corollary adverse impact on U.S. consumers who must pay more while the U.S. patent owner sells the same product in other markets at lower prices.

The Federal Circuit does not explain why U.S. consumers should surplus-fund R&D for the benefit of foreign consumers. If U.S. manufacturers need to secure a certain level of revenue to fund R&D, the responsibility for that revenue should be spread out among the global consumer base. In theory, U.S. manufacturers may need to raise prices in foreign markets and lower prices in the U.S. market under a rule of international exhaustion, in other words, move towards global prices. Benefits should accrue to U.S. consumers who would pay something between the former U.S. "surplus" price and the adjusted global price, assuming that the pre-international exhaustion U.S. price was higher.

B. Facilitating global supply chains

As this Court observed in *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. ___, 133 S.Ct. 1351, 1365-66 (2013), the manufacture of products sold and used in the United States relies on an extensive network of supply chains spanning the globe. Although 2017 political discourse in the United States may envision some import/export rebalancing as a means to promote domestic manufacturing, the globally distributed nature of productive resources will not within the foreseeable future transform the U.S. economy into an autarky. The typical computer product sold within the United States is likely to contain microprocessors

manufactured within the United States,[24] but the preponderance of other parts are most likely to have been produced in foreign countries, and the computer itself is likely to have been assembled outside the United States.[25] A substantial part of the components of each computer are likely to be protected by U.S. patents, including those parts produced outside the United States.[26] Absent a doctrine of international exhaustion, or express consent by each owner of a U.S. patent for each part, the owner of each and every patent covering a part in the computer has the right to prevent the importation of that computer into the United States – despite the lawful purchase of each and every part outside the United States. The same for the ubiquitous cellular telephone and other smart devices marketed and sold throughout the United States.

The Federal Circuit dismissed concern with supply chain interference on grounds that, insofar as it was aware, *Jazz Photo* had not resulted in the types of supply chain problems suggested by Petitioner and various *Amici*. In *Kirtsaeng v. Wiley*, this Court rejected a similar argument regarding copyright as was

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[24] *See, e.g.*, Falan Yinug, *Made in America: The Facts about Semiconductor Manufacturing, Semiconductor Industry Association* (SIA), August 2015.

[25] *See, e.g.*, Brett Berger and Robert F. Martin, *The Growth of Chinese Exports: An Examination of the Detailed Trade Data*, Board of Governors of the Federal Reserve System, International Finance Discussion Papers, Number 1033, November 2011, at 8-9.

[26] *See, e.g.*, Robert Hackett, *These tech companies scored the most patents in 2014*, FORTUNE – TECH, Updated: Feb. 24, 2015, http://fortune.com/2015/02/24/most-patents-companies-2014/, accessed January 14, 2017.

made by the Federal Circuit with respect to patents, observing, inter alia, "we believe that the practical problems that petitioner and his *Amici* have described are too serious, too extensive, and too likely to come about for us to dismiss them as insignificant – particularly in light of the ever-growing importance of foreign trade to America." 133 S.Ct. at 1367.

It is difficult to gauge the supply chain impact of *Jazz Photo* because most patent enforcement issues are dealt with outside the courts. It may well be that there are significant supply chain interruptions taking place. *Amici* representatives of the electronics industry and various manufacturing industries are better placed to gauge the effect-in-fact of *Jazz Photo*.

If this Court formally endorses national exhaustion, it is reasonable to assume that there will be more interest among U.S. patent holders in the potential for blocking product imports. Cf., *Kirtsaeng*, 568 U.S. ___, 133 S.Ct. at 1366. If some patent-owning manufacturing companies choose not to enforce certain rights, this is not a sound reason to validate those rights.

III. Potential constraints on high pharmaceutical prices

A. Stakeholder interests

The United States is an advanced economy with substantial aggregate wealth. The U.S. government has largely avoided controlling the prices of medicines,

including patented medicines.[27] Prices for patent-protected originator pharmaceutical products in the United States substantially exceed prices for the same products in other countries.[28] If parallel imports of medicines are allowed,[29] downward pricing pressure will be imposed on patented pharmaceuticals in the United States.[30] For this reason, the originator pharmaceutical industry has staunchly opposed a rule of international exhaustion of patents and corollary parallel imports.[31]

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[27] *See, e.g.*, Jim Hahn, *Federal Drug Price Negotiation: Implications for Medicare Part D*, Congressional Research Service, RL33782, January 5, 2007.

[28] *See* U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, December 2004.

[29] With respect to patents, "parallel imports" refer to import goods patented in the importing country (here, the United States), when such goods are first placed on the market outside that country under the authority of the patent owner. *See* Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 JOURNAL OF INTERNATIONAL ECONOMIC LAW 607, 608 (1998).

[30] *See* HHS Taskforce Report, at 65-80. The HHS Taskforce Report concluded that the overall effect on prices in the United States was likely to be modest based on factors alluded to in this *Amicus* Brief as well.

[31] The term "originator" is customarily used to refer to the party that first obtains approval from the drug regulatory authority for the commercial marketing of a drug. In the United States, that authority is the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS).

At its heart, the parallel imports question for the United States asks whether this country has a policy preference to facilitate high pharmaceutical prices, and to avoid measures that may ameliorate those high prices.

The patent-owning originator industry argues that high prices are necessary for supporting research and development (R&D) that is vital to the American public. It is, however, inappropriate to correlate high pharmaceutical prices enabled by patents with the interests of the public in pharmaceutical innovation. First, originator pharmaceutical companies invest approximately 15-20% of their revenues in R&D.[32] The industry spends a higher percentage of its revenues on advertising and promotion, including direct to consumer advertising, than it does on R&D.[33] It is doubtful that downward pricing pressure created by parallel imports would result in a material decline in the funds available for investment in R&D, particularly as there is substantial room to reallocate budgets. Second, a very substantial part of pharmaceutical R&D funding in the United States comes from the National Institutes of Health with a budget of approximately $30

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[32] *See* U.S. International Trade Administration, *2016 Top Markets Report: Pharmaceuticals*, at 3.

[33] *See, e.g.*, Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC News, Business, November 6, 2014, http://www.bbc.com/news/business-28212223, accessed January 15, 2017.

billion per year, most of which is directed toward pharmaceutical and pharmaceutical-related R&D.[34] There is no reason to think that this budget would diminish if pharmaceutical prices are lower. Just as likely, because federal government expenditures (such as through the Veterans Administration) on pharmaceuticals would decline, more funding would be available to and through NIH. Third, as explained in some detail in the Senate Staff Report on Sovaldi, industry practices with respect to pricing are not based on the interests of the

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[34] According to the National Institutes of Health:

"The NIH invests nearly $32.3* billion annually in medical research for the American people.

More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world.

About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.

*This amount reflects the sum of discretionary budget authority of $31,381 million received by NIH in FY 2016 under The Consolidated Appropriations Act of 2016, Public Law (P.L.) 114-113, $780 million derived from PHS Evaluation financing, and mandatory budget authority of $150 million for special type 1 diabetes research authorized per P.L. 113-93 and P.L. 114-10. Details regarding current appropriations are available from the Office of Budget."

U.S. Department of Health and Human Services, National Institutes of Health, *What we do*, https://www.nih.gov/about-nih/what-we-do/budget, accessed January 15, 2017. According to webpage, information last updated on April 4, 2016.

American public, but rather on the interests of capital markets, return on investment and executive compensation.[35] In the case of Sovaldi, the only evident constraint with respect to pricing was the upper limit of public health budgets. Fourth, as explained below, the price impact of parallel imports of patented pharmaceutical products into the United States is likely to be modest.

Pharmaceutical patent owning enterprises routinely sell their products on foreign markets at prices substantially below those secured on the U.S. market. The principal reason for this is that most governments outside the United States place some form of price control on pharmaceutical products.[36] Pharmaceuticals are essential to public health and are sold in markets that are affected by patent protection and other regulatory barriers.[37] Patient demand for important pharmaceutical products is "inelastic" in the sense that purchasers who materially depend on pharmaceutical

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[35] Staff of S. Comm. on Fin., 114th Cong., *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, 106-10 (Comm. Print 2015).

[36] PHARMACEUTICAL PRICES IN THE 21ST CENTURY (Zaheer-Ud-Din Babar ed., Springer Int'l Publ'g Switz. 2015) (including country contributions); OECD Health Policy Studies, *Pharmaceutical Pricing Policies in a Global Market* (2008); U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries* (2004).

[37] Frederick M. Abbott, *Parallel Trade in Pharmaceuticals: Trade Therapy for Market Distortions*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY EXHAUSTION AND PARALLEL IMPORTS 145-65, eds. I. Calboli & E. Lee, Edward Elgar Pub. (2016) [hereinafter "Abbott – Parallel Trade"]; and HHS Taskforce Report.

products for their well-being or life do not have a choice other than to procure the product.[38] Demand for life-saving products is limited only by the ability of the individual patient or public health system to pay. Absent government intervention in the pricing system, pharmaceutical patent owning companies may charge high (and in some cases excessive) prices for their products without suffering falloff in demand. Governments have a responsibility to use public resources responsibly, as well as to prevent excessive burdens on private patients.

In the United States, pharmaceutical patent owning companies are largely able to charge the prices that the "free market" will bear. Although state procurement authorities, the Veterans Administration and other governmental authorities use various approaches to secure better prices, there are not "price controls" as such, and the Medicare drug benefit system precludes the federal government by law from negotiating prices with the pharmaceutical industry.[39]

When the holder of a pharmaceutical patent in the United States sells or authorizes the sale of the corresponding patented product in a foreign country it may well be selling at a price below the price that would be

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[38] Sean Flynn, Aidan Hollis, and Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, JOURNAL OF LAW, MEDICINE & ETHICS, 2009, Summer; 37(2): 184-208.

[39] Jim Hahn, *Federal Drug Price Negotiation: Implications for Medicare Part D*, Congressional Research Service, RL33782, January 5, 2007.

charged for the same product in the United States.[40] From a business standpoint, it is profitable to make the sale because the price for the patented pharmaceutical is typically far in excess of the cost of production and distribution. In the United States, for example, generic versions of previously patented drugs typically sell for a very substantial discount to the "on patent" price, and still at a profit.[41]

At least in the context of copyright, this Court has previously recognized that a first sale in the United States exhausts the intellectual property right regardless whether the relevant product is thereafter exported and re-imported.[42] There is no reason to expect that this result should be different with respect to patents so that under current law, notwithstanding the Federal Circuit decisions in *Jazz Photo* and in the instant case below, pharmaceutical products first sold in the United States and exported should not be subject to patent infringement actions upon re-importation.

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[40] *See* references in note 36, *supra*.

[41] *See, e.g.*, Letter from Government Accountability Office to Sen. Orrin Hatch, January 31, 2012, re: GAO-12-371R Savings from Generic Drug Use, stating: "On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug."

[42] *Quality King Distributors, Inc. v. L'anza Research Intern., Inc.*, 523 U.S. 135, 118 S.Ct. 1125 (1998).

Under current U.S. law, the re-import of prescription pharmaceutical products manufactured in and exported from the United States requires the consent of the manufacturer.[43]

Under a rule of international exhaustion, wholesalers engaged in price arbitrage would seek to buy patented drugs outside the United States and import them into the United States to take advantage of price differentials.[44]

HHS and the FDA control the importation of pharmaceutical products into the United States through measures requiring that such products placed on the market in the United States must be approved for commercial marketing, and a requirement that foreign manufacturing facilities producing for export to the United States are inspected and approved by FDA inspectors.[45] The adoption by this Court of a rule of international exhaustion of patent rights would not affect these requirements. Exhaustion of patents in the United States requires that a product be placed on the market by or with the consent of the patent owner (although there may be limited exceptions to this consent requirement as in the case of compulsory licensing of a patent directed by a court as a remedy in an antitrust

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[43] *Lexmark International, Inc. v. Impression Products, Inc.*, 816 F.3d at 766.

[44] HHS Taskforce Report.

[45] *See, e.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §381(a); and HHS Taskforce Report.

proceeding). Should this Court adopt a rule of international exhaustion, patented pharmaceuticals imported pursuant to that rule would still be produced abroad with the consent or authorization of the U.S. patent owner at an FDA inspected and approved facility. Should parallel imports of patented pharmaceutical products be allowed under a rule of international patent exhaustion, it is reasonable to assume that HHS may as necessary or appropriate adapt its regulatory requirements to further address the circumstances of parallel importers.[46]

Congress has authorized HHS to allow imports by pharmacists and wholesalers of "prescription drugs" from Canada,[47] though so far HHS has decline to exercise this authority.[48] There is also provision for individual waivers for imports from Canada by individuals for personal use, and in other circumstances deemed to be appropriate.[49]

It is unlikely that products supplied to foreign markets will dramatically alter pricing practices in the United States because of supply and demand limitations and controls.[50] Assume for the sake of argument, given relative market size, that the volume of demand

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[46] *See*, for example, requirements under 21 U.S.C. §384(d).

[47] 21 U.S.C. §384(b).

[48] *See* HHS Taskforce Report.

[49] 21 U.S.C. §§381(d)(2) & 384(j).

[50] Regarding the complex elements of international trade in pharmaceuticals, *see* Abbott – Parallel Trade. Data analysis in HHS Taskforce Report.

for a particular patented product is roughly equivalent in the aggregate in the United States and the European Union.[51] Assume further that a pharmaceutical originator is required by price controls, in the aggregate, to sell in the European Union at a 30% discount to the price charged in the United States.[52] If wholesale arbitrageurs attempt to buy the entire stock of patented pharmaceutical products placed on the market in the EU and ship them to the United States, consumers in Europe (*e.g.*, hospitals, patients, insurance companies, public health authorities) would need to seek a resupply for the entire stock. Or, consumers in Europe would go without medicines.

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[51] According to recent data from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the combined revenues from pharmaceutical sales in the United States and Canada were more than double European pharmaceutical sales in 2015 (48.7% of world market and 22.2% of world market, respectively). These numbers reflect dollar cost rather than volume, and so reflect pricing differentials as well as other factors. The population of the European Union is somewhat higher than the combined population of the United States and Canada. European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical Industry in Figures, Key Data 2016, at 14, www.efpia.eu, accessed January 15, 2017.

[52] The international Trade Administration Report on Pharmaceutical Price Controls in OECD Countries based on 2003 data, suggested that in the absence of OECD price controls, revenues from on-patent sales would increase 25 to 38%. This excluded a group of lower income OECD countries. We can infer from this that patented drug prices in Europe are in the order of magnitude of 30% lower than in the United States (i.e., if removing price controls would increase revenues in that range). U.S. Department of Commerce, International Trade Administration, *supra* note 36, at pages 19-20.

It seems highly doubtful that wholesalers in Europe would be able to purchase the entire stock of medicines available there because of the existing relationships between procurement authorities and suppliers. Some probably modest percentage of such products could be purchased and exported to the United States. Arbitrageurs would mark up the prices to provide themselves a profit. Ultimately, some modest percentage of pharmaceutical products destined for Europe might be available on the market in the United States. This is consistent with the conclusion reached by the HHS Taskforce on Drug Importation in its 2004 report, which took account of a variety of pharmaceutical supply and regulatory constraints.[53] Even then because of the complex and concentrated way the pharmaceutical distribution structure in the United States is organized, there are a number of hurdles to overcome in selling those products in the United States market.[54] Ultimately, there would probably be some downward pressure on prices in the United States, but

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[53] The Report stated: "We find that savings from legalizing drug imports would likely be a small percentage of total drug spending, a finding similar to that of the Congressional Budget Office." HHS Taskforce Report, at 67.

[54] *See* 2015 MDM Market Leaders, Top Pharmaceuticals Distributors, stating: "Three companies generate about 85% of all revenues from drug distribution in the United States," http://www.mdm.com/2015-top-pharmaceuticals-distributors, accessed January 15, 2017; and U.S. Department of Justice and Federal Trade Commission, *Competition Issues in the Distribution of Pharmaceuticals, Contribution from the United States*, OECD Global Forum on Competition, DAF/COMP/GF/WD(2014)43, February 10, 2014.

not the 30% difference between U.S. prices and European prices.

The originator pharmaceutical industry has taken a great interest in blocking parallel imports and its *Amici* are likely to do so before this Court. The interests of the American public and the originator pharmaceutical industry should not be conflated. The American public has a more compelling interest in mechanisms that can restrain originator pharmaceutical pricing than the industry does in maintaining its present profit margins.

B. Voluntary discrimination in favor of low income countries

The originator patent owning pharmaceutical companies argued as early as the late 1990s that a rule of international exhaustion would preclude them from continuing to sell medicines in low income countries at discounted prices because of the potential for re-export to high income countries,[55] although when those arguments were first made it was questionable whether the industry in fact offered patented medicines for sale at low prices in low income countries.[56] Today, a number

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[55] *See, e.g.*, Harvey E. Bale, Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 JOURNAL OF INTERNATIONAL ECONOMIC LAW 637 (1999).

[56] This *Amicus* first raised the issue of discriminatory pricing in favor of low income countries at a meeting on competition law at UNCTAD in 1999, with a substantial number of delegations from Africa present. African delegates attending that meeting expressed surprise at the position of the pharmaceutical originators,

of originator companies are selling or licensing for sale certain patented products at discounted prices in low income countries.[57]

As a matter of public health policy, the United States should not discourage discount pricing of patented pharmaceuticals in favor of low income countries.[58] A rule of international exhaustion for the United States does not interfere with such pricing practices. Patent owners and licensees selling under discount programs in favor of low income countries can and should be allowed to restrict exports of the supplied products by contract. There is no need to provide a cause of action for patent infringement regarding importation into the United States.

Pharmaceutical products sold at discount prices to low income countries are typically purchased by government public procurement authorities, often

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stating that to their knowledge discounted pharmaceuticals were not available in their countries. That discussion was noted in Frederick M. Abbott, *Second Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of the Exhaustion of Intellectual Property Rights and Parallel Importation* (September 6, 2000), available at SSRN: https://ssrn.com/abstract=1921856.

[57] *See, e.g.*, Medicines Patent Pool, Five Years of Patent Pooling for Public Health, Annual Report 2015, and more recent updates on licensing arrangements at http://www.medicinespatentpool.org/, accessed January 15, 2017.

[58] Governments and patient populations in low income countries typically lack the financial means to purchase patented pharmaceutical products at prices charged in higher income countries. Prices of generic products sold at marginal cost are often unaffordable without subsidization.

supported by third country financial assistance.[59] Government procurement authorities purchasing under such contracts do not have an interest in the re-export of the subject products needed to address local requirements, including because procurement is monitored by external funders.[60] Even assuming some margin for wrongdoing among procurement authorities, because the actors in this arena are repeat players, it is unlikely that large-scale diversion of such products would take place.

In addition, if there are difficulties enforcing contractual restraints on exports, governments in low income countries can impose legal restrictions on exports for the purpose of protecting public health programs. This would be permitted under WTO rules, at the least by use of the General Agreement on Tariffs and Trade

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[59] *See, e.g.*, The Global Fund, Sourcing & Management of Health Products, stating:

> "Over the 2014-2016 period, the Global Fund will provide more than US$10 billion to countries for programs to combat the three diseases and help build health systems. Approximately half of that amount will go toward the procurement and management of health products. In 2013, that amounted to almost US$1.8 billion." http://www.theglobalfund.org/en/sourcing/, accessed January 15, 2017.

[60] *Id.*, The Global Fund, Monitoring and Evaluation, http://www.theglobalfund.org/en/me/, http://www.theglobalfund.org/en/sourcing/, accessed January 15, 2017. *See also, e.g.*, U.S. Department of State, Office of Inspector General, U.S. Agency for International Development, *Worldwide Audit of USAID's Procurement and Distribution of Commodities for the President's Emergency Plan for AIDS Relief*, Audit Report No. 9-000-09-011-P, August 13, 2009.

(GATT) Article XX(b) exception in favor of protecting public health.[61] If the potential for imports of low priced U.S.-patented pharmaceutical products from low income countries becomes a genuine concern, Congress could act to expressly limit such imports under the GATT Article XX(b) exception as a measure necessary to protect public health in those low income countries. The WTO 30 August 2003 waiver in favor of compulsory licensing for export recognizes the importance of precluding diversion of products imported under special programs, obligating beneficiary members to take measures to prevent re-export.[62] None of these approaches requires recognition of post-sale restrictions based on patents. Defense of discriminatory pricing in favor of low income countries does not require the United States or any other country to forgo the general benefits of a rule of international patent exhaustion.

CONCLUSION

Prior to the decision of the Federal Circuit in *Jazz Photo*, preponderant authority in the United States, including by this Court, pointed toward a rule of international exhaustion of patent rights. Application of the

[61] General Agreement on Tariffs and Trade 1994, April 15, 1994; Marrakesh Agreement Establishing the World Trade Organization, Annex IA, art. XX(b), 1867 U.N.T.S. 187 (1994).

[62] WTO, Decision of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 2 September 2003, paras. 4 & 5. The waiver also requires members to have available legal means to prevent importation of products improperly diverted from the system.

first sale rule to U.S. patents when a first sale takes place outside the United States involves the application of U.S. law within the United States. There is no impingement on foreign law or foreign prerogative. International agreements to which the United States is a party permit adoption of a rule of international exhaustion.

Amici representing the electronics industry and other industry sectors are presenting arguments supporting international exhaustion as important to facilitating efficient global supply chains, reducing prices to American consumers and for other reasons. This *Amicus* supports that "general case."

A rule of international exhaustion of patent rights will exert downward pressure on pharmaceutical prices in the United States. This downward pressure is likely to be relatively modest in light of the nature of the global pharmaceutical supply market. Nonetheless, it will be a step in the right direction. This Court should approach with great caution arguments advanced by the originator pharmaceutical industry about the potential negative impact of a rule of international exhaustion. The decision of the Federal Circuit below should be reversed with respect both to its rejection of international exhaustion of patent rights, and to its sustaining of patent-based post-sale restrictions. This

Court should adopt a rule of international exhaustion of patent rights for the United States, and preclude post-sale restrictions based on patents.

Respectfully submitted,

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